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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,101	05/03/2002	Chiara Malvolti	217941USOPCT	2555
22850	7590	10/04/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,101	MALVOLI ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05/03/02</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Receipt is acknowledged of preliminary amendments and the three status request letters.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 are vague and indefinite for reciting the term "derivative". The metes and bounds of this term are not disclosed in the specification.

Claim 5 recites the limitation "the acetal derivative" according to claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "an acetal derivative".

Claim 10 is vague and indefinite for failing to clearly point out the claimed subject matter. It is not clear what requirements the claim is referring to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saidi et al (6,241,969 B1) in view of Davis (Physico-chemical studies on aerosol solutions for drug delivery \pm Water-propylene glycol systems).

Saidi teaches aqueous compositions containing corticosteroids as the active agent for the treatments of ailments and diseases of the respiratory tract, the compositions comprising the corticosteroid in an aqueous based carrier for delivery via nebulizer. The corticosteroid may be budesonide or flunisolide, and the pH of the solution may be from 4 to 8 (col. 6, lines 10-65). The solution may contain a cosolvent such as propylene glycol, ethanol or polyethylene glycol (col. 5, lines 15-21). The total amount of the cosolvent can be from 0.1 to about 20 percent by weight (col. 8, lines 1-17). Saidi also discloses a method of preparing the said formulation which includes heating the cosolvent to about 50°C (col. 8, lines 35-37). Saidi lacks disclosure on the specific water-polyethylene glycol ratio.

Davis discloses nebulizer solutions containing a water-propylene glycol system. The said system is to deliver a solution of a steroid to the patient's lungs via a nebulizer (see page 71, summary). The suitable steroid is flunisolide and table 1 shows various solubility and aerosol output for flunisolide at various propylene glycol concentration ranges. Davis also discloses various water:propylene glycol ratios for the formulation and suitable particle size for the droplets. Davis lacks disclosure on the use of budesonide.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Saidi et al on solutions of steroids such as budesonide and flunisolide dissolved in an aqueous base solvent for nebulization to have looked in the art for specific water to polyethylene glycol ratios as disclosed by Davis, with reasonable expectations of successfully preparing formulations that are stable and effective with the active dissolved in a suitable solvent/carrier system.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (Physico-chemical studies on aerosol solutions for drug delivery I Water-propylene glycol systems) in view of Blondino et al (6,004,537).

Davis discussed above, lacks disclosure on the use of budesonide.

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Blondino discloses pharmaceutical solution aerosol formulations containing budesonide and solvents. The solution formulations contain about 3% by weight of budesonide.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Davis on solutions of steroids for nebulization to have looked in the art for other and specific steroids suitable for solution formulations such as budesonide, as disclosed by Blondino, with reasonable expectations of successfully preparing formulations that are stable, effective and useful for various treatments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'MH' with a stylized flourish.

Mina Haghighatian
September 28, 2004